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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,796	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 16, 2005 has been entered.

Formal matters

2. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

3. Claims 1, 39 and 44-46 have been amended as requested in the amendment of Paper filed on September 29, 2005. Claims 1 and 39-46 are pending in the instant application.

4. Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to an invention nonelected by original presentation, there being no allowable generic or linking claim (see section 2 of Paper mailed on March 09, 2004).

5. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

7. Applicant's arguments filed on May 16, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claim 1, as amended, is rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of a peptide. The instant application does not disclose a specific biological role for this peptide, or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Claim 1 is drawn to an isolated biopolymer marker of SEQ ID NO: 1 or of SEQ ID NO: 4. Briefly, the instant specification describes the finding of the specific fragments of fibronectin precursor protein, which are polypeptides of SEQ ID NOS: 1-6, in a serum sample treated according to a protocol provided on pages 40-46 of the instant specification. These fragments were asserted to be "related to Type II diabetes" (page 47, line 2 of the instant specification). This finding is further extrapolated into an assertion that peptides of SEQ ID NO: 1 and SEQ ID NO: 4 could be useful as a marker for Type II diabetes. The state of the art is such that it does

not recognize any specific association of the polypeptide of SEQ ID NO: 1 or SEQ ID NO: 4 with any particular disease state in general or with type II diabetes in particular.

Furthermore, the instant specification fails to explain the relationship between a polypeptide of SEQ ID NO: 1 or SEQ ID NO: 4 and Type II diabetes. The text on page 47 states that "Figures 1 and 3 are photographs of a gel indicative of the presence/absence of the marker in disease vs. control and, in cases where the marker is always present, the relative strength, e.g. the up or down regulation of the marker relative to categorization of disease state is deduced". While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding the following questions must be answered. Is it "the up or down regulation of the marker relative to categorization of disease state"? Or is "the presence/absence" of the polypeptide of SEQ ID NO: 1 or the polypeptide of SEQ ID NO: 4 indicative of a disease? What is the critical level of up or down regulation that is predictive of a disease state or predictive of type II diabetes?

A specification can meet the legal requirements of utility and enablement for a new peptide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new peptide, or a well-established utility for the claimed peptide would be readily apparent to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed peptide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed peptide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. Alternatively, a hypothetical

specification could disclose that a claimed peptide is expressed at specific altered levels in colon cancer as compared to healthy colon tissue. One skilled in the art would immediately recognize that the peptide in hypothetical example would be useful as a colon cancer marker. However, such is not the fact pattern here. The instant specification discloses that "a biopolymer marker which is strongly present in a normal individual, but is down-regulated in disease is predictive of said disease; while alternatively, a biopolymer marker which is strongly present in a disease state, but is down-regulated in normal individuals, is indicative of said disease state" (page 11 of the instant specification). Thus, it appears that in order to practice the claimed invention a skilled practitioner would have to engage in significant further research to determine if peptides of SEQ ID NO: 1 or SEQ ID NO: 4 are absent or present or strongly present in all or any tissue samples of a person suspected having Type II diabetes, or is up- or down-regulated in disease in order to establish if the claimed peptide could be used as a marker for Type II diabetes. However, it is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.

Therefore, to accept Applicant's claim for a "biopolymer marker" irrespective of any recitation of intended use in the claim or lack of support for asserted utility to use the claimed peptide for diagnosis of Type II diabetes, would be comparable to use the peptides of SEQ ID NO: 1 and SEQ ID NO: 4 as an object of future research. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that decision had a known structure and molecular weight it could have readily been

employed as a molecular standard at that time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well-known process of combustion for purposes of lighting and/ or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

Applicant's arguments traversing the enablement requirement in Response submitted on May 16, 2005 are answered in so far as they are relevant with respect to the instant utility rejection. It is further noted that Applicant refers to the alleged amendment to claim 1 "to recite that the isolated biopolymer markers are linked to Type II diabetes" (bottom at page 19 of the Response). However, claim 1, as presented, does not contain any reference to Type II diabetes, therefore, Applicant's arguments with respect to this intended amendment are moot.

At pages 21-29 of the Response, Applicant presents explanations of the results presented in Figure 1 and argues that "one of ordinary skill in the art would be able to compare the established mass spectrum profile of an isolated biopolymer marker selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO: 4 to a mass spectrum profile obtained from a patient's sample to confirm the presence or absence of a peak at about 1630 daltons, wherein the presence of the claimed biopolymer markers is indicative of a link to Type II diabetes". Applicant's arguments have been fully considered but are not persuasive for the following reasons.

First, it appears that Applicant's statement that it is "the presence of the claimed biopolymer markers [in a sample] is indicative of a link to Type II diabetes" is not supported by

the instant specification, as filed. The Examiner failed to find any reference that would clearly indicate that finding of peptides of SEQ ID NO: 1 or of SEQ ID NO: 4 in a sample would be indicative of a link to Type II diabetes. Second, Applicant's explanation of the data as presented in the originally filed Figures 1 and 2 appears to contradict Applicant's own statement because band 1 is clearly present in lanes 7-9 of Figure 3, which correspond to normal control patients (bottom at page 22 continuing to page 23 of the Response).

At page 23 of the Response, Applicant submits that "[c]laim 1, as amended herein, does not recite that the claimed isolated biomarkers are diagnostics for Type II diabetes, nor does it recite that the claimed isolated biomarkers are related to Type II diabetes, even though Applicants believe that the instant specification as originally filed fully supports both of these recitations". While it is true that the claim, as amended, does not include any limitations as to what the claimed peptides are diagnostic for, the issue at hand remains that in order to satisfy the utility requirement under 35 U.S.C. 101, the claimed peptides must have a specific and substantial credible utility. If the instant biopolymer markers of SEQ ID NO: 1 and of SEQ ID NO: 4 are not diagnostics for Type II diabetes, then it is not obvious why they are named markers. For example, if a peptide of SEQ ID NO: 1 was found in a sample obtained from a patient, what would that mean to the skilled practitioner? Does it mean that a patient has Type II diabetes, or is at risk of developing the disease? At present, it appears that the only information obtained from identifying the presence of a marker of SEQ ID NO: 1 or of SEQ ID NO: 4 is the determination of "a link to Type II diabetes". One skilled in the art readily appreciates that many factors have a link to or are associated with a particular pathological condition. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court specifically stated that "a patent is not a

hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion". The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. In the instant case the claimed biopolymer markers of SEQ ID NO: 1 and of SEQ ID NO: 4 are only useful for further research to establish their specific and substantial utility.

With respect to Applicant's reasoning on pages 26-36, there appears to be no disagreement with Applicant's argument regarding the value of proteomics research in identifying proteins that "may prove to be a useful drug target or diagnostic marker" (top at page 33); moreover, Applicant's cited articles all appear to relate to importance of scientific research to identify potential and possible future diagnostic tools, and the Examiner does not dispute that too.

To grant Applicant a patent encompassing isolated fragments of a naturally occurring human protein, which are not readily usable in their current form, would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed peptides based solely upon an assertion that the protein is linked to Type II diabetes is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted.

Thus, since the instant specification does not disclose a credible "real world" use for the isolated biopolymer markers of SEQ ID NO: 1 and of SEQ ID NO: 4 in currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

November 2, 2005